It is believed that no Extension(s) of Time is(are) required and no fees are due for this response. However, should the U.S. Patent and Trademark Office determine that any Extension of Time is required for this submission, Applicants respectfully request that this document also be considered as a Petition for the appropriate Extension(s) of Time and that any required Extension(s) be granted. Should any fee be due or any refund be owed for this application (including any required Extension fees), the Commissioner is hereby authorized and requested to charge the required fee(s) and/or credit the refund(s) owed to our Deposit Account No. 04-0100.

REMARKS

The Office Action indicates that Applicants' amendments filed on September 3, 2002 have been entered so that claims 1-44 and 54-62 are currently pending in this application. However, the Office Action requires a restriction of those pending claims to one of the following groups:

Group I: Claims 1-20 and 54-62 drawn to an isolated nucleic acid and kit; and

Group II: Claims 21-43, drawn to a method of detecting DISC1 allelic variants.

In addition, the Examiner has also required election of a particular nucleic acid sequence (specified by its SEQ ID NO.) for examination. More specifically, the Office Action indicates that a single "reference" nucleic acid sequence must be elected from among

SEQ ID NOS:1 and 4; that a single DISC1/DISC2 polymorphism must be elected from among SEQ ID NOS:33-43; and that a single pair of nucleic acid primers must be elected from among SEQ ID NOS:44-127.

In order to be fully responsive to this second Requirement for Restriction, Applicants hereby provisionally elect, with traverse, to prosecute the claims of Group I (*i.e.*, claims 1-20 and 54-62) directed to isolated nucleic acids and/or kits. In addition, Applicants also provisionally elect with traverse for these claims to be examiner with respect to the reference nucleic acid sequence set forth in SEQ ID NO:1, the allelic variant set forth in SEQ ID NO:33 and the primer sequences set forth in SEQ ID NOS:44 and 45. However, Applicants respectfully traverse the Requirement for Restriction and reserve the right to petition therefrom under 37 C.F.R. § 1.144 and for the reasons set forth below.

GROUPS I AND II SHOULD BE EXAMINED TOGETHER

At the outset, Applicants wish to again respectfully point out that the restriction of claims directed product and process of use in this application is improper and should be withdrawn. Although M.P.E.P. § 806.05(h) may provide that such claims must ordinarily be restricted, the patent statute provides an exception for biotechnological processes under 35 U.S.C. § 103(b). In particular, 35 U.S.C. § 103(b)(1) states in relevant part that:

> [A] biotechnological process using or resulting in a composition of matter that is novel . . . and nonobvious . . . shall be considered nonobvious if --

> (A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and (B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.

35 U.S.C. § 103(b)(2) then goes on the mandate that (emphasis added):

> A patent issued on a process under Paragraph (1) [of 35 U.S.C. § 103(b)] (***A) shall also contain the claims to the composition of matter*** used in or made by that process, or (B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent.

Hence, compliance with Section 103(b) of the patent statute necessitates that claims directed to a biotechnological process (in this instance methods for detecting DISC1 or DISC2 allelic variants) **MUST** be examined with claims to the composition(s) of matter used in that process so that any patent issuing on the process will also contain claims to the composition(s) of matter, as required under 35 U.S.C. § 103(b)(2).

Moreover, 35 U.S.C. § 103(b) clearly establishes that the examination of claims for the biological process and compositions used for that process cannot be a serious burden for the Examiner. Under 35 U.S.C. § 103(b), the biological process must be novel and non-obvious if the composition of matter is found to be non-obvious. Thus, the Examiner need only perform a single search to determine whether the compositions of matter are non-obvious. Once the Examiner determines that the compositions of matter

are non-obvious then, pursuant to 35 U.S.C. § 103(b), the biological processes using those compositions of matter must also be novel and non-obvious. See also, *In re Ochiai*, 37 USPQ2d 1127 (Fed. Cir. 1995).

Under Patent Office examining procedures, "if the search and examination of an entire application can be made without serious burden, the Examiner ***must*** examine it on the merits, even though it includes claims to distinct or independent inventions." M.P.E.P. § 803 (emphasis added). As explained above, it is not a serious burden to examine the claims of Groups I and II in a single application, and such examination is mandated by 35 U.S.C. § 103(b). Therefore, Applicants respectfully request that the claims of Groups I and II be rejoined and examined together in this application.

THE NUCLEIC ACIDS OF THIS INVENTION ARE PROPERLY ELECTED AS SEPARATE SPECIES OF A COMMON GENUS

The Office Action indicates that election of the separate nucleic acid sequences in this application is not a species election. Applicants respectfully traverse this part of the Restriction Requirement as well, and submit that the separate nucleic acid sequences should be examined together, as species of a common genus.

In particular, and contrary to what is stated in the Office Action, the sequences of SEQ ID NOS:1 and 4 are related. SEQ ID NO:1 corresponds to a cDNA sequence that encodes a DISC1 polypeptide (see, *e.g.*, from page 7, line 10 to page 9, line 2 of the specification). SEQ ID NO:4 is a sequence of genomic DNA corresponding to a segment of human chromosome which contain the DIS1 genomic sequence.

Similarly, the sequences set forth in SEQ ID NOS:33-43 represent exemplary polymorphisms of the DISC1 gene that have been discovered by Applicants and are part of the present invention. All of these polymorphisms are linked by a single inventive concept: that polymorphisms in the DISC1 gene (and, hence, in its genomic sequences) co-segregate with neuropsychiatric disorders (for example schizophrenia) and can therefore be used to diagnose and/or treat such disorders. Hence, these individual sequences represent separate species of Applicants' generic invention; namely, polymorphisms of the DISC1 gene (both cDNA and genomic sequences) that may be commonly used to diagnose and/or treat neuropsychiatric disorders (for example, schizophrenia). Similarly, the nucleic acid sequences recited in SEQ ID NOS. 44-127 all have a single, related utility that is described in the application as filed. Specifically, these sequences may all be used as primers, in generic methods of amplifying and detecting DISC1 polymorphisms.

37 C.F.R. § 1.146 provides that, where an application contains a generic claim to a generic invention (for example claim 1 of this application), the Applicants may pursue claims to both the generic invention and for a reasonable number of species. For all of the foregoing reasons, Applicants again respectfully submit that the Restriction between individual nucleic acids is improper and should be withdrawn in favor of a species

election requirement. In so doing, Applicants respectfully request that the above election of SEQ ID NOS:1, 33 and 44-45 be treated as a species election.

Respectfully submitted,

Dated: November 25, 2002

Samuel S. Woodley, Ph.D.
Reg. No. 43,287
Agent for Applicants

DARBY & DARBY, P.C.
Post Office Box 5257
New York, NY 10150-5257
Phone (212) 527-7700